VDH VIRGINIA DEPARTMENT OF HEALTH

VIRGINIA'S HEALTH IS IN YOUR HANDS.
Do your part, stop the spread.

Testing for COVID-19

COVID-19 Testing Guidance and Assistance for Virginia's Overnight Camps

May 5, 2021

Agenda

- Welcome & Introductions
- Review of EO Requirement and new CDC Testing Guidance for Overnight Camps
- Testing Guidance Summary for Overnight Camps
- Overview of Testing Options
- Performing Antigen Tests
- Q & A

Executive Order 72
Overnight Summer Camps and Testing

Executive Order 72 requires camps to implement a plan that requires every camper attending an overnight camp to have:

- **A negative molecular test within seven (7) days prior to the beginning of camp**

OR

- **A 14-day symptom screening for the camper and all persons in their household.** Campers utilizing symptom screening must restrict their close contacts to Family members for the duration of the 14-day period

CDC Guidance

Operating Youth and Summer Camps During COVID-19

- Ask campers and staff who are not fully vaccinated to provide proof of a negative viral test taken no more than 1–3 days before arriving at camp. Delay arrival for campers or staff with confirmed positive test results.

- For camp sessions that last at least one week, screening testing should be done 3–5 days after arrival at camp in accordance with CDC travel guidance. Fully vaccinated asymptomatic people without an exposure can refrain from routine screening testing

- Weekly **screening testing** of unvaccinated staff who may oversee multiple cohorts of campers over the summer will help identify those who are asymptomatic and do not have known, suspected, or reported exposure of the virus that causes COVID-19 and prevent further transmission.

CDC Guidance

Operating Youth and Summer Camps During COVID-19

Overnight Camps should have a plan to isolate staff or campers with symptoms immediately, and at a minimum, **a plan to refer symptomatic persons for viral testing. Some camps may have plans in place to conduct diagnostic viral testing onsite.**

Persons with symptoms should remain isolated until the test result is returned. Medical care should be provided as needed, as per camp health protocols.

- If the test result is negative, the person should remain in isolation until his or her symptoms have improved according to existing camp policies (typically, 24 hours without fever and no use of fever-reducing medication).

- If the test result is positive, the person should remain in isolation for at least 10 days after symptom onset, and 24 hours without fever without use of fever-reducing medication, and other symptoms have improved.

Considerations

- Establish and maintain a working relationship with your local health department
- Review the VDH Antigen Testing Recommendations for guidance and algorithms for antigen test interpretation
- Familiarize yourself with VDH's guide to contact tracing
- Review the VDH When it is Safe to be Around Others: Ending Isolation in Non Healthcare Settings Infographic

Testing Guidance Summary- Overnight Camps

Pre-Camp

Post-Arrival
(3-5 days after arrival)

Regular Screening Testing of Unvaccinated Campers and Staff and Referral to/Provision of Diagnostic Testing

Diagnostic Testing

- Testing for symptomatic individuals – those individuals exhibiting signs and symptoms of COVID-19

- Testing for asymptomatic individuals who have been identified as a close contact of someone infected with COVID-19
  - Close contacts include everyone in the infected person's household cohort and anyone else who was within 6 feet of the infected person for a cumulative total of 15 minutes or more over a 24-hour period. The definition of a close contact applies **regardless of whether either person was wearing a mask**.

  - An infected person can spread SARS-CoV-2 starting from 2 days before they have any symptoms (or, for asymptomatic patients, 2 days before the positive specimen collection date), until they meet criteria for discontinuing home isolation.

  - The test should occur **no sooner than day 4 or 5 after the last exposure**. (In other words, if an exposure lasted several days, the best time to test is 4 or 5 days after the end of the exposure period.)

What is Screening Testing?

Screening testing is intended to proactively identify infected people who may be contagious as early as possible so measures can be taken to prevent further transmission of illness. *It is estimated that asymptomatic or presymptomatic individuals account for* ***more than 50%*** *of COVID-19 transmissions.*

Considerations for Screening Testing and Overnight Summer Camps

Weekly screening testing of unvaccinated staff who may oversee multiple cohorts of campers over the summer will help identify those who are asymptomatic and do not have known, suspected, or reported exposure of the virus that causes COVID-19 and prevent further transmission.

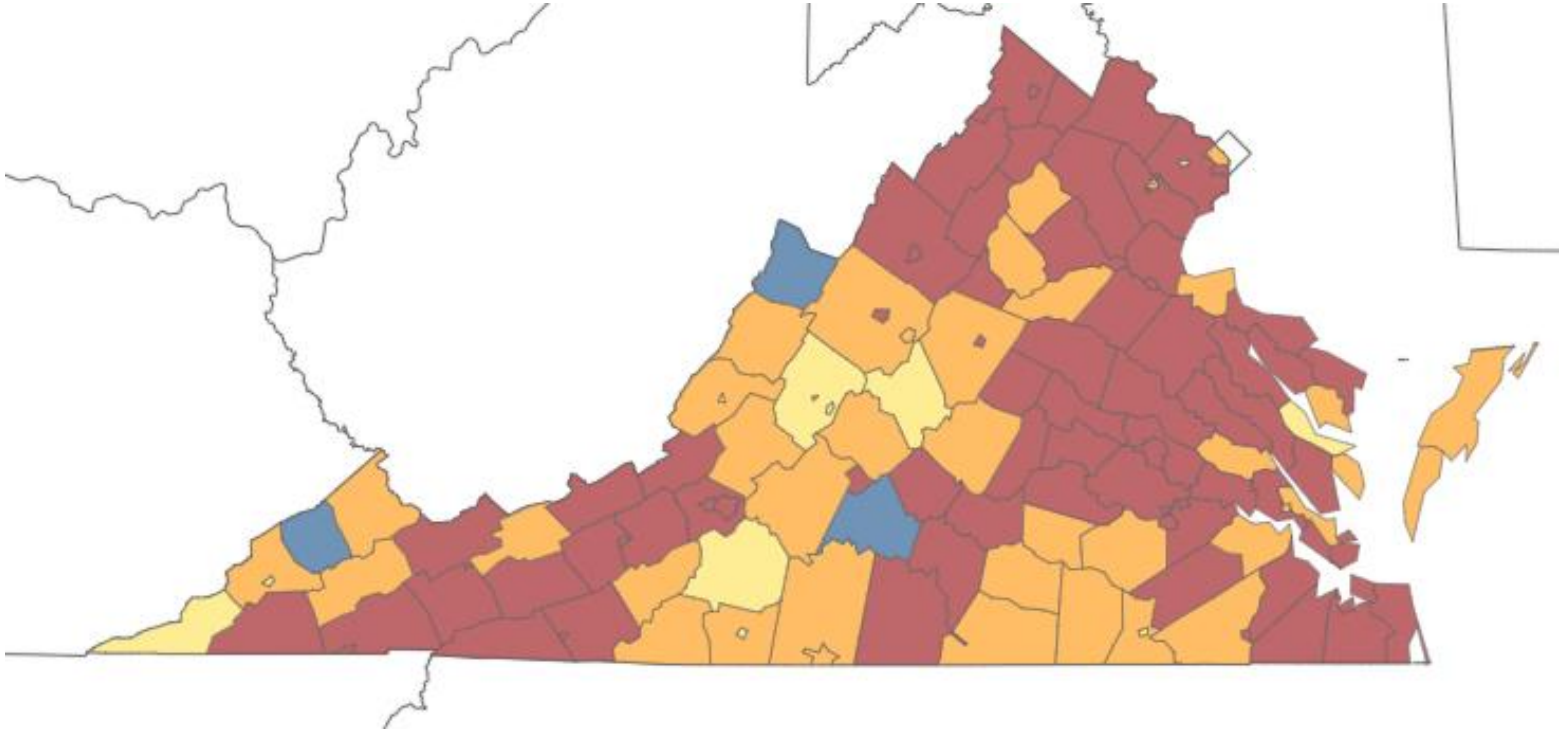
CDC: Testing Recommendations by Level of Community Transmission

<table>
<tr><th>LOW</th><th>MODERATE</th><th>SUBSTANTIAL</th><th>HIGH</th></tr>
<tr><td colspan="4">Diagnostic testing: Symptomatic Teachers, Staff, students AND close contacts referred for testing
Screening testing for teachers and staff: expanded screening for teachers and staff at least weekly.</td></tr>
<tr><td>No screening testing for students</td><td colspan="3">Screening testing for students offered at least once per week</td></tr>
<tr><td colspan="2">Testing for high-risk sports: for schools conducting routine screening testing for sports, testing recommended at least once per week

Testing for low-risk and intermediate risk sports: for schools conducting routine screening testing for sports, testing recommended at least once per week</td><td colspan="2">Testing for high-risk sports: for schools conducting routine screening testing for sports, testing recommended at least twice per week

Testing for low and intermediate risk sports:for schools conducting routine screening testing for sports, testing recommended at least once per week</td></tr>
</table>

CDC Guidance: Assessing Level of Community Transmission



Indicator - If the two indicators suggest different transmission levels, the higher level is selected	**Low Transmission Blue**	**Moderate Transmission Yellow**	**Substantial Transmission Orange**	**High Transmission Red**
Total new cases per 100,000 persons in the past 7 days	0-9.99	10-49.99	50-99.99	≥100
Percentage of NAATs[1] that are positive during the past 7 days	0-4.99%	5-7.99%	8-9.99%	≥10.0%

https://www.vdh.virginia.gov/coronavirus/key-measures/pandemic-metrics/school-metrics/

VDH VIRGINIA DEPARTMENT OF HEALTH

COVID-19 Test Types Overview

Antigen diagnostic test

- Detects current infection using a nasal swab with an immunoassay that detects the presence of a target viral protein (antigen)
- Can use a machine or card much like a home pregnancy test (15 mins)

Polymerase Chain Reaction (RT-PCR) test

- Molecular diagnostic test detects current infections using a nasal or throat swab specimen and a PCR machine that replicates RNA is used to detect COVID-19. Both lab-based and on-site PCR tests are available.

Testing Resources from VDH

VDH has Abbott BinaxNOW COVID-19 Antigen Cards available, free of charge. Prescription needed.

Camp Requirements and VDH Support

In addition to **providing testing supplies at no cost**, VDH will provide support to camps:

Camps must:	VDH will provide:
Physician Order: acquire a signed standing order for COVID-19 testing with Abbott BinaxNOW from a physician (or other prescriptive authority)	
CLIA Certificate of Waiver: receive a CLIA Certificate of Waiver OR partner with an entity with a CLIA Certificate to perform tests	Guidance on CLIA Certificate of Waiver and **assistance with application process**
PPE: supply PPE for staff involved in testing process and ensure staff have reviewed CDC guidance on the use of PPE	**Guidance on obtaining PPE** from local emergency management
Training Requirements: ensure all staff administering Abbott BinaxNOW tests have completed necessary online training modules	Link to **Abbott BinaxNOW online training**
Consent and Notification Processes: receive signed consent for each individual being tested and establish notification processes for all positive test results and close contacts	**Consent form templates,** materials to share with staff and families, and FAQ sheets that schools can customize for their own use
Reporting Requirements and Follow Up: register for the VDH reporting portal and report all test results daily	**Training sessions** on using the VDH reporting portal and on daily reporting
Biohazard Waste: have means to safely dispose of used testing material	
Plan for Safe Isolation and Quarantine: develop procedures to support all those tested who may require isolation or quarantine	Collaboration with camps on any needed **contact tracing, isolation/quarantine, or mitigation guidance**
Additional Considerations Provide **physical space** to conduct testing safely and privately, ensure **confidentiality** of results and protect privacy, maintain information to refer tested individuals to **confirmatory testing** when needed	VDH will also provide: • assistance during planning process • antigeninfo@vdh.virginia.gov for ongoing questions and support

Resources for Camp Testing - Toolkit for K-12 can be used for camps

1. Camps must **review the Readiness Review Checklist** and define a plan to meet requirements..

2. Camps will **send a completed Readiness Review Checklist to the VDH Central Office** Testing Team to indicate intent to conduct testing at antigeninfo@vdh.virginia.gov

3. VDH Antigen Testing Team will review the checklist to ensure requirements are met, and if so, send the camp the link to complete the **VDH antigen test request form**.

4. VDH Central Office Testing Team will **inform the relevant local health district point-of contact** of the camp's request status and interest in the program.

5. Upon receipt of the completed VDH antigen test request form, **VDH Antigen Testing Team will distribute BinaxNOW tests** to the camp.

VDH published a Toolkit on the VDH website to support this process. The Toolkit includes:

1. Overview of Diagnostic Testing Program / Overview of Screening Testing Program
2. Readiness Review Checklist
3. K-12 Statewide Standing Order - *n/a for camps*
4. Additional Testing Sites in the Community
5. Testing Program Cover Letter Templates (Staff, Student)
6. Sample Consent Forms (Staff, Student)
7. Diagnostic Testing FAQs / Screening Testing FAQ
8. Testing Protocols for School Scenarios
9. K-12 Testing Algorithm
10. K-12 BinaxNOW Process Flow
11. Test Result Tracker Template
12. Results Notification Letter Template

Requirements to Conduct Antigen Testing

A facility must:

- **Obtain CLIA Certificate of Waiver** – all point-of-care antigen tests are CLIA waived
- **Training –** Abbott offers online training; Abbott also offers webinar
- **Prescriber** – someone with prescriptive authority must write for the test and review the result
- **Report results to VDH** – test results need to be reported to VDH via reporting portal

Overall, requirements are not difficult to fulfill

- VDH can help with training and has guidance documents regarding use of antigen testing

Requesting Antigen Tests from VDH

To Order Abbott BinaxNOW Ag Cards, contact:
antigeninfo@vdh.virginia.gov

All additional questions on antigen test distribution can be directed to
Antigeninfo@vdh.virginia.gov

CLIA

Clinical **Laboratory** Improvement Amendment

-Federal program ensuring quality lab testing.

The phrase “CLIA Certified” means having a CLIA Certificate.

*A **CLIA Certificate of Waiver** is a type of certificate issued by CLIA.*

Facilities that have a CLIA Certificate of Waiver can perform tests that are classified as CLIA Waived by the FDA or have a FDA EUA for a waived testing environment.

Do I already have a CLIA Certificate?

Check the CDC search https://www.cdc.gov/clia/LabSearch.html

or CMS CLIA lab look up at: https://qcor.cms.gov/main.jsp

How do I apply for a CLIA Certificate?

CMS 116: CLIA Application for Certification

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

FACILITY ADDRESS — *Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*
NUMBER, STREET *(No P.O. Boxes)*

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*
NUMBER, STREET

CITY	STATE	ZIP CODE

CITY	STATE	ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*
NUMBER, STREET

CITY	STATE	ZIP CODE

NAME OF DIRECTOR *(Last, First, Middle Initial)*

CREDENTIALS

FOR OFFICE USE ONLY
Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*
☐ Certificate for Provider Performed Microscopy Procedures (PPM) *((Complete Sections I-VII and IX-X)*
☐ Certificate of Compliance *(Complete Sections I – X)*
☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ AOA ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

PRA Disclosure Statement
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

☐ 01 Ambulance
☐ 02 Ambulatory Surgery Center
☐ 03 Ancillary Testing Site in Health Care Facility
☐ 04 Assisted Living Facility
☐ 05 Blood Bank
☐ 06 Community Clinic
☐ 07 Comp. Outpatient Rehab Facility
☐ 08 End Stage Renal Disease Dialysis Facility
☐ 09 Federally Qualified Health Center
☐ 10 Health Fair
☐ 11 Health Main. Organization
☐ 12 Home Health Agency
☐ 13 Hospice
☐ 14 Hospital
☐ 15 Independent
☐ 16 Industrial
☐ 17 Insurance
☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
☐ 19 Mobile Laboratory
☐ 20 Pharmacy
☐ 21 Physician Office
☐ 22 Practitioner Other *(Specify)*
☐ 23 Prison
☐ 24 Public Health Laboratories
☐ 25 Rural Health Clinic
☐ 26 School/Student Health Service
☐ 27 Skilled Nursing Facility/ Nursing Facility
☐ 28 Tissue Bank/Repositories
☐ 29 Other *(Specify)*

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?
☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   ☐ Yes ☐ No
   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ☐ Yes ☐ No
   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ☐ Yes ☐ No
   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Identify the PPM testing (to be) performed. Be as specific as possible.
e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)* **DATE**

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Keep a copy of the application for yourself and **mail the signed original** to our office at:

Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, VA 23233-1485

Emailed applications can only be accepted if they contain a password protected digital signature. We will happily review your application prior to submission. **Email to: CLIALAB@vdh.virginia.gov**

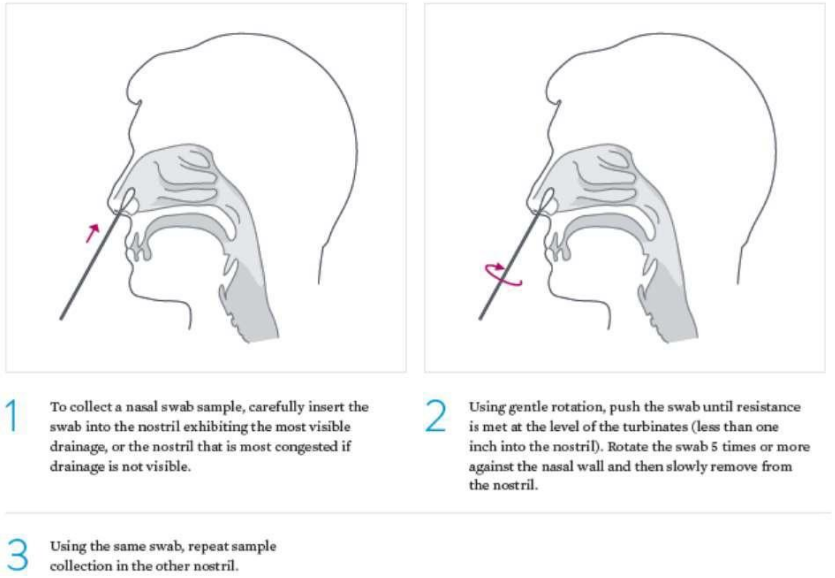
If the application is time sensitive, we recommend **overnight delivery**.
No money is due with the application. Certificate of Waiver fees are $180 for a two (2) year certificate. Once you get your CLIA number, the fee can be paid the next day on-line at **pay.gov**

BinaxNOW™ COVID-19 Ag Card Overview

Nasal Swab Sample Collection

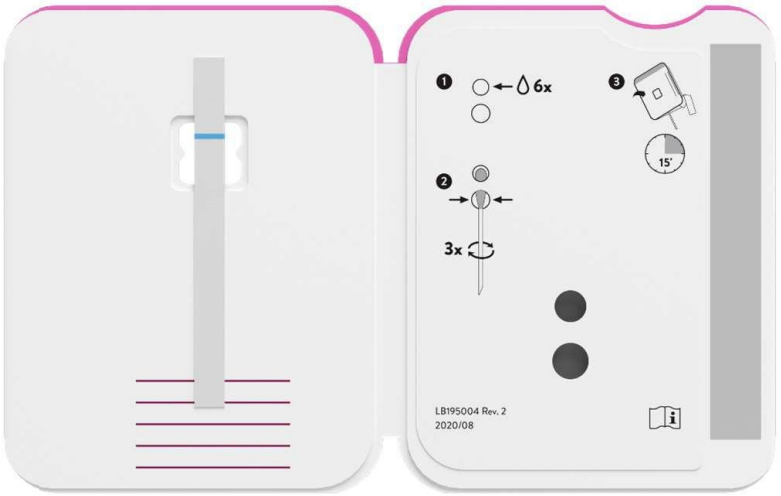
Only the swab provided in the kit is to be used for nasal swab collection

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
  - At the level of the nasal turbinates
  - Less than one inch into nostril
- Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 15 seconds
- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril



BinaxNOW™ COVID-19 Ag Card Overview

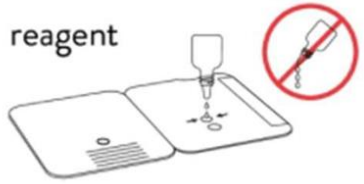
Exterior View



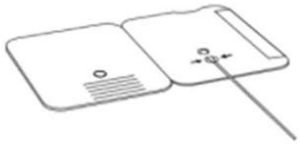
Interior View

BinaxNOW™ COVID-19 Ag Card Test Procedure Overview

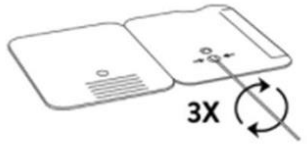
1. Add the extraction reagent



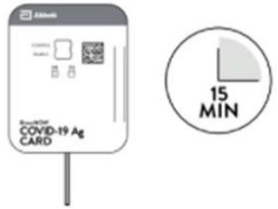
2. Insert the sample nasal swab



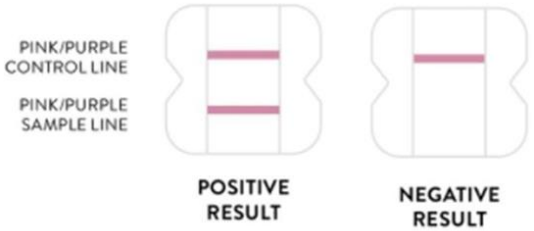
3. Rotate the nasal swab shaft three times



4. Close the test card; wait 15 minutes



5. Results are read visually



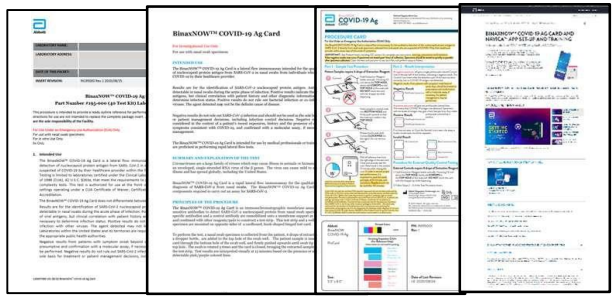
distribute

Training Toolkit

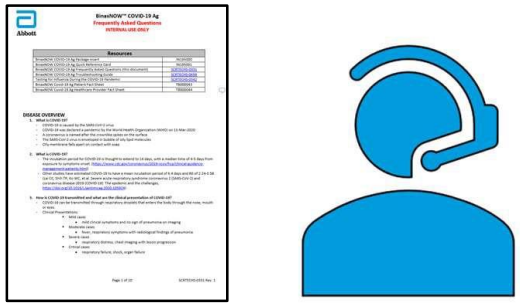
https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Six Detailed Training Videos

PowerPoint Training



Helpful Tools & Support Documents



FAQs and Technical Service Contacts
Monday-Friday 8am EST – 8pm EST 1-800-257-9525 or ts.scr@abbott.com

distribute

Training Requirements

Nothing needs to be submitted to VDH

Keep training documentation for facility's records.

Every facility must document who has completed training and is proficient in operating the test.

https://www.vdh.virginia.gov/emergency-preparedness/training-education/

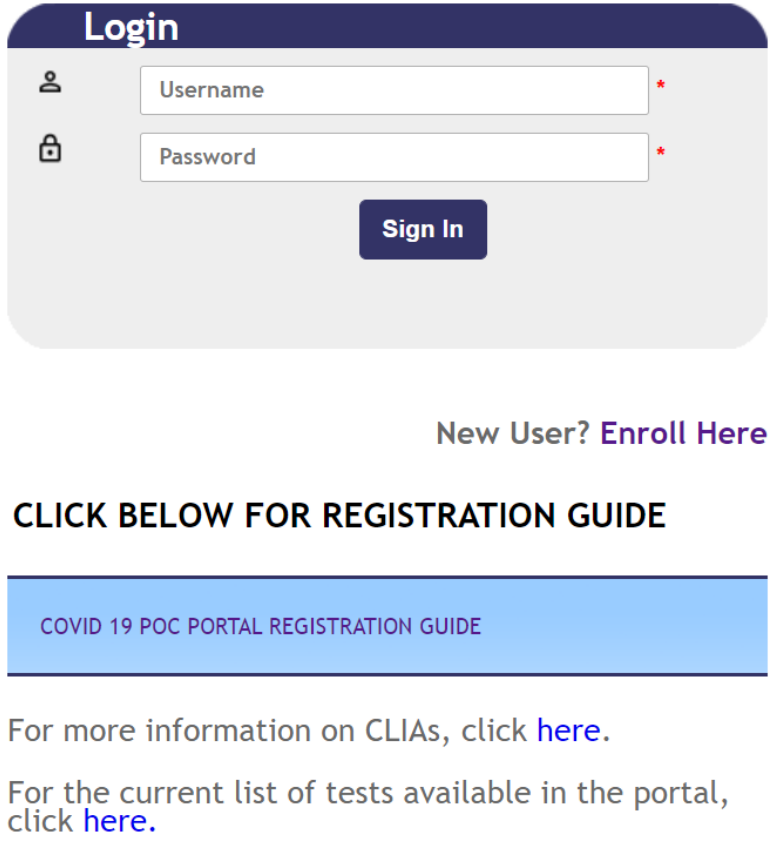
- Nasal swab collection, competency checklist, other training resources

Reporting Results

Report BOTH positive and negative results within 24 hours using the VDH's Reporting Portal for Point-of-Care (POC) Test Results: https://apps.vdh.virginia.gov/pocreporting/login/login.aspx

This site may be used to meet the rapid reporting requirement for POC tests and allows for aggregating negative results for high-volume sites. Positive results must be reported as a single entry.

Creating a Portal Account



Create an account before beginning to test. New accounts can sometimes take 2-3 days to gain access to the portal.

For Reporting Portal Questions email: POCReporting@vdh.virginia.gov

Resources

VDH K-12 Testing Guidance

VDH Antigen Testing Recommendations

VDH's guide to contact tracing

VDH When it is Safe to be Around Others: Ending Isolation in Non Healthcare Settings Infographic

VDH Summer Camp Guidance

CDC's Guidance for Operating Youth and Summer Camps during COVID-19

Field Guide for Camps on Implementation of CDC Guidance

Questions?